REMARKS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, and 110 are pending. By this amendment claims 25, 27, 50, 52, 54, 79, and 83 have been amended and new claim 110 has been added. Support for the amendments to the claims is provided, for example, by claims 26, 50, 53, and 79, and the specification at pages 22, 29, 32, 33, and 36. Support for new claim 110 is provided, for example, by claims 42, 70, and 84, and the specification at pages 23 and 33. No new matter has been introduced.

Applicants thank the Examiner for extending examination to claims 26 and 50. In the Disposition of Claims section of the Office Action, only claim 94 is withdrawn from consideration, and on page 2 of the Office Action, examination has been extended to claims 26 and 50, but claims 26, 50, and 94 are indicated as withdrawn at page 9 of the Office Action. Also, claims 26 and 50, but not claim 94 has been rejected in the present Office Action. However, claims 27 and 54 are rejected in the present Office Action. Thus, it appears that only claim 94 stands withdrawn and the statement on page 9 that claims 26, 50, and 94 are withdrawn is not correct. Pending Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, and 109 are rejected in the present Office Action.

As indicated in the last response, in the September 16, 2004 Ex Parte Quayle Action, the elected species indicated as allowable were: (1) durum wheat as the plasticized matrix material and (2) a probiotic neutraceutical component as an encapsulant. Applicant notes that the Examiner has indicated in the present Office Action that the species durum wheat as the plasticized matrix material is not allowable and the rejections encompass the originally elected species. Accordingly, it appears that the probiotic nutraceutical component as an encapsulant is no longer indicated as an allowable species, and that the election of species requirement is still maintained for the plasticized matrix material, the encapsulant, the additional matrix material, and the encapsulant form. The claims readable on the elected

species are Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110.

Applicants also thank the Examiner for withdrawing all of the previous rejections over the references. New grounds of rejections over newly cited references have been made, and the previous rejections under 35 U.S.C. 112, second paragraph have been maintained.

THE REJECTIONS UNDER 35 USC 112, SECOND PARAGRAPH

Claims 25-31, 34, 35, 37, 38, 42, 46, 50, 52-59, 61, 62, 64-67, 69,70, 73, 75, 79, 82, 83, 91-93, 95-97, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner maintains that the term "at least about" 40% is indefinite because by adding the term "least" it cannot be determined where the lower limit lies. However, it is clear that use of the term "at least" sets the lower limit to "about 40%" as one ordinarily skilled in the art would glean from the context of the present specification where it is disclosed that:

> The matrix material is used in an effective encapsulating amount. In embodiments of the present invention, the matrix material content, such as the starch content of the particles may be at least about 40% by weight, for example from about 60% by weight to about 95% by weight, based upon the weight of the final product.

The Examiner, further, asserts that it cannot be determined if "at least about" 40 encompasses 10% as in the case for cyclodextrin or 5% for guar. However, the claim recites that the weight percentage refers to the weight of "at least one matrix material", so the lower limit of 5% guar or 10% cyclodextrin would be included with other matrix materials to obtain a matrix content of about 40% or more or "at least about 40%".

The Examiner also cites MPEP 2173.05(b) and *Amgen v. Chugai*, 18 USPQ2d 1016, and states that the term "about" permits flexibility, particularly where there is nothing in the record to indicate the precise metes and bounds of the term. However, applicant's specification gives specific examples and ranges which indicate the precise metes and bounds of the term. In Chugai, the court stated that it was only after the "at least 120,000" claims were cancelled that GI submitted the "at least about 160,000" claim language, and the "addition of the word 'about' seems to constitute an effort to recapture ... a mean activity somewhere between 120,000, which the patent examiner found was anticipated by the prior art, and [the] 160,000 IU/AU" claims which were previously allowed. However, in the present case, the original specification supports use of the phrase "at least about 40%", and the claims are not amended to include the addition of the word "about" to recapture a broader range as in Chugai. The Court in Chugai cautioned that

> ...our holding that the term "about" renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims. It may be acceptable in appropriate fact situations, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed.Cir.1983) ("use of 'stretching ... at a rate exceeding about 10% per second' in the claims is not indefinite"), even though it is not here.

See, *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1219 (Fed. Cir. 1991).

Clear guidance is given in the present specification to those skilled in the art to employ an effective encapsulating amount of matrix material as recited in the present specification at page 12 second full paragraph, and the working Examples give specific amounts and Table 2 at page 42 give specific ranges for amounts. It is accordingly submitted that the rejection on the grounds that the term "at least about" is indefinite should be withdrawn.

The Examiner also maintains that the term "substantially" in claims 25, 37, 52, 64 and 83 is a relative term which renders the claim indefinite. According to the Examiner,

phrases such as homogeneous, non-expanded" and "non-cellular" are definite phrases, and include some inherent degree of variation insofar as a perfectly "homogeneous" composition and a perfectly "non-expanded" and "non-cellular" structure is merely an ideal, it is unclear what modifying function the term "substantially" serves in this context. The term "substantially" makes it clear that the terms it is used in conjunction with should not be interpreted as requiring perfection or an ideal, and that variations which do not adversely affect desired release properties of the product may be included. The present specification provides clear guidance to those skilled in the art as to mixing and extrusion conditions for obtaining a substantially homogenous mixture, to obtaining a substantially non-expanded, non-cellular structure, and avoiding substantial dextrinization of starch at, for example, page 22 line 12 to page 27 line3, and page 29 lines 9-13 where exemplary specific densities are provided, and at pages 22, 29,, 32, 33, and 36 where conditions for avoiding excessive dextrinization are provided.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTION UNDER 35 U.S.C. 103

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Lentz et al (EP 404,727) in view of newly cited Newton et al (U.S. Patent No. 4,938,967). This rejection is respectfully traversed.

Lentz et al does not teach or suggest the use of a plasticized mass comprising starch which is not substantially dextrinized, or particles where an encapsulant is dispersed throughout the plasticized mass of each particle, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims.

The Examiner maintains that Lentz et al. disclose thermoplastic polymer compositions comprising a destructurized starch and a polymer comprising a hydroxyl group (component b) and the compositions further contain additives as well as hydrophobic, substantially water-insoluble polymers. The Examiner points out that the thermoplastic

starches have the ability to be extruded and molded and are blended with hydrophobic thermoplastic materials and show a surprising increase in all or a part of their physical properties and behavior of their melts. The starches employed by Lentz et al, it is indicated, show an improved dimensional stability in humid air whilst retaining a surprisingly high degree of disintegration in contact with moisture water which in consequence leads to a high degree of biodegradability (page 3, lines 13-20).

Clearly, Lentz et al employs a starch which disintegrates unexpectedly rapidly in water to provide a high degree of biodegradability. The destructurized starch of Lentz has been heated to a high enough temperature and for a time long enough so that the specific endothermic transition analysis as represented by differential scanning calorimetry (DSC) indicates that a specific relatively narrow peak just prior to oxidative and thermal degradation has disappeared. See page 1 of the specification, lines 25-44. The reference teaches away from thermoplastic starch because processing parameters such as water content, temperature, and pressure are generally critical, and must be narrowly controlled to achieve reproducible quality products. See page 1, lines 37-40.

Lentz desires destructuring of starch and degradation to achieve rapid water solubility and rapid biodegradability, and does not teach or suggest avoidance of substantial dextrinization of starch. As disclosed in the present specification, high shear is directly related to high specific mechanical energy, which in turn increases the molecular destructurization and dextrinization of starch. Breakdown of the starch molecules, and in particular the amylopectin, increases the solubility of the extruded starch composition in aqueous systems. As disclosed in the present specification, high water contents, and low shear and low extruder screw speeds are employed to avoid substantial dextrinization of starch and to provide a controlled release of encapsulant rather than an unexpectedly rapid disintegration in water for unexpectedly high biodegradability. See pages 3, 6, 7, 9, 22, 29, 32, 33, and 36 of the present specification.

The Examiner points out that Lentz et al discloses that the polymer compositions may be formed into granules and powder and they may act as carrier materials for active

agents, and may be mixed with active ingredients such as pharmaceuticals and/or agriculturally active compounds such as insecticides or pesticides for subsequent release applications of these ingredients. According to the Examiner, the components may be mixed into the compositions, thus encompassing a homogeneous mixture. However, mixing the active ingredients with the polymer composition granules or powder would result in coating of the active ingredients on the granule or powder particles and would not result in a particle with the active ingredient being dispersed throughout a plasticized mass as claimed.

Newton et al does not cure the deficiencies in the disclosure of Lentz et al, and even if the references were properly combinable, applicant's claimed invention would not be obtained. The Examiner employs Newton et al as teaching to show the general conditions of the art when formulating pharmaceutical compositions. The Examiner admits that Newton et al does not disclose a plasticized matrix in the disclosed dosage forms, and that Lentz et al does not disclose the size of granules made from the compositions or the amount of active agent in a granule.

The Examiner maintains that it would have been obvious to formulate capsules comprising pellets or granules when formulating pharmaceutical compositions with the matrices of Lentz et al motivated by the desire to formulate a conventional dosage form with conventional parameters such as the density as disclosed by Newton et al. However, Newton et al desires to increase gastric residence time by increasing density which is the opposite effect of an unexpectedly rapid disintegration in water. Also, to increase density, Newton et al employs a weighting agent with a density of at least 2.5 g/ml in an amount of 50% by weight, based on the dry weight of the unit, which is an inorganic compound such as magnesium trisilicate, magnesium oxide, aluminum oxide, zinc oxide , and the like. See Newton et al at col. 9 line 51 to col. 10, line 18. Combining the disclosures of the references as proposed by the Examiner simply would not result in nor render obvious a particle with the active ingredient being dispersed throughout a plasticized mass comprising a starch which is not substantially dextrinized as claimed.

As to the amount of matrix material and as to the release profile recited in claims 38 and 65, the Examiner maintains that it would take no more than routine skill in the art to adjust the amount of binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65. However, there is no reason to increase the release time desired by Lentz et al because it is contrary to the reference's teaching and desire for an unexpectedly rapid disintegration in water.

Additionally, with regard to claims 82 and 85 none of the references teach or suggest the encapsulation of an enzyme or microorganism and none of the references teach or suggest the encapsulation of a liquid encapsulant as claimed in claim 93.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 42, 69, 70, 84, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Lentz et al (EP 404,727) in view of newly cited Newton et al (U.S. Patent No. 4,938,967) in further view of newly cited Jane et al (U.S. Patent No. 5,397,834. This rejection is respectfully traversed.

The Examiner points out that Jane et al disclose biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein, that suitable starches include those derived from durum wheat, and that the reference differs from the instant claims in so far as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Jane et al does not cure the deficiencies in the disclosures of Lentz et al and Newton et al discussed above, and even if it were obvious to combine the teachings of Lentz et al, Newton et al, and Jane et al, applicant's claimed invention would not be obtained nor rendered obvious. The Examiner maintains that Lentz et al and Newton et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. As discussed above, Lentz et al and Newton et al do not employ a plasticized mass comprising a starch which is not substantially dextrinized and Lentz et al specifically

teaches away from a thermoplastic starch. Even if it were obvious to employ a starch derived from durum wheat in the product of Lentz et al, which it is not, Applicant's claimed products would not be obtained nor rendered obvious.

If a starch derived from durum wheat were employed in the product of Lentz et al it would be destructured and heated to a high enough temperature and for a time long enough so that the specific endothermic transition analysis as represented by differential scanning calorimetry (DSC) indicates that a specific relatively narrow peak just prior to oxidative and thermal degradation has disappeared. There is no teaching or suggestion to employ a plasticized mass comprising starch which is not substantially dextrinized. Moreover, a starch which is derived from durum wheat is not the same as durum wheat which has different matrix forming properties and different release properties. Durum wheat contains gluten which forms a plasticizable starch-protein matrix, and as disclosed in the present invention, heating or cooking of durum wheat to gelatinize starch is not required. Use of starch derived from durum wheat would not include the gluten and would result in a different matrix and different release properties.

The rejection is untenable and reconsideration and withdrawal thereof is respectfully requested.

CONCLUSION

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

It is not believed that any additional fees are due. However, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,

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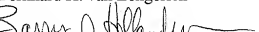

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